

# Notice of Allowability

Application No.

09/439,594

Examiner

Joyce Tung

Applicant(s)

RABBANI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/31/2003.
2. ☒ The allowed claim(s) is/are CLAIMS 146-200 (CLAIMS 1-55).
3. ☒ The drawings filed on 12 November 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 12/31/20093
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

## REASONS FOR ALLOWANCE

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/31/2003 has been entered. Claims 146-200 are pending.

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on 12/31/2003 is in compliance with 37 CFR 1.56 and 1.97-198. Accordingly, the information disclosure statement is being considered by the examiner.

3. The following is an examiner's statement of reasons for allowance:

No prior art has been found teaching or suggesting the process for detecting the presence of a specific target nucleic acid sequence comprising providing initial primers or nucleic acid constructs comprising two segments (A) a first segment (i) being sufficiently complementary to a first portion of said specific nucleic acid sequence to bind to which provides for template-dependent extension, and (B) a second segment being (i) substantially non-identical to the first segment, (ii) substantially identical to a second portion of said specific nucleic acid sequence, (iii) which binds to complementary sequences that are synthesized by extension of the first segment of said first initial primers with said specific target nucleic acid as a template and

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wherein the absence of a denaturation step, the first initial primers or first nucleic acid construct participate in the formation of a stem-loop structure after said specific target nucleic acid sequence is used as a template for extension, incubating the specific nucleic acid sequence and the initial primers or the nucleic acid construct in the presence of substrate, buffer and template dependent polymerizing enzyme, self-annealing between said second segment of said first initial primer or first nucleic acid construct and a segment formed after target template dependent extension of the first segment of said first initial primer or the nucleic acid construct, separating said first segment of said first initial primer or the nucleic acid construct from said specific target nucleic acid sequence and detecting the presence of said stem-loop structures formed in the previous step.

The closest prior art is the reference of Honeyman et al. (Am. J. Vet. Res. 1999, Vol. 60, pg. 734-737). Honeyman et al. disclose a method of snapback SSCP analysis for genotyping Golden Retrievers for the X-linked muscular dystrophy alleles (See pg. 734 column 1). The method involves a snapback primer (See pg. 735, column 1, first paragraph). Honeyman et al. do not disclose the snapback primer which has the same features as the claimed initial primer which function differently from the snapback primer of Honeyman et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung JT  
April 9, 2004

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

4/14/04